K133894

MAR 1 8 2014

510(k) SUMMARY

Prepared for:	**TERUMO EUROPE N.V.** **Interleuvenlaan 40,** **3001 Leuven,** **BELGIUM**
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Date prepared:	**December 2013**

Note: Class III Summary & Certification is not applicable for the submission of a Class II device

II. 510(k) SUMMARY

1. Device Name
2. Reason for Submission
3. Intended Use
4. Description
5. Substantial Equivalence
6. Additional Safety Information
7. Summary of Verification Activities
8. Additional Safety Information
9. Conclusion

510(k) SUMMARY as required by 807.92
Summary of Safety & Effectiveness Information

Submitter information

Prepared for:	TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM
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Date prepared:	December 2013

1. Device Name

Proprietary Name

SURFLO® Winged Infusion Set with Filter and Needle Protection (Surshield®)

Classification Name

Intravascular Administration Set (-FPA)

21 CFR, Section 880.5440

Classification: Class II

2. Reason for Submission

This premarket notification [510(k)] is being submitted for the 23G and the 25G Surflo Winged Infusion Set with Filter and Needle Protection (Surshield), to provide supporting information that despite of some changes in material, design, process and labeling to the devices cleared under K070547, the proposed devices are safe and effective and substantially equivalent to the devices cleared under K070547.

3. Intended Use

The Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) is intended to access the peripheral vascular system, for single-dose or short-term intravenous administration of fluids using a syringe or other compatible/appropriate devices. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needle stick.

Note: This is the same intended use as the predicate device, Surflo Winged Infusion Set with Filter and Needle Protection (Surshield), cleared under K070547.

4. Description

The 23G and the 25G Terumo Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield), are sterile, single use devices consisting of a needle attached to a winged hub, microbore tubing, adapter with integrated 20 µm filter and adapter cap, and a hinged shield cover that attaches to the wing just below the needle-to-wing junction.

The shield cover can be turned 180 degrees on the hinge. As the needle is removed from the patient's vessel, the user's finger actively pushes the shield cover until it latches onto the needle using a one- or two- handed technique. An audible click is noted upon activation. The shield cover is

designed to allow the user's finger to remain behind the needle point so that the risk of needle stick injury is minimized. The shield cover is transparent for easy confirmation of the needle held in it.

The device possesses a 350 mm length microbore tubing.

5. Substantial Equivalence

The 23G and the 25G Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield), manufactured by Terumo Europe N.V., submitted in this 510(k) file are substantially equivalent in intended use, description/specifications, technology/principles of operation, materials and performance to the following cleared devices:

Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) (K070547) (SV-S23FL35VS & SV-S25FL35VS), manufactured by Terumo Europe N.V.

Differences between the devices do not raise any significant issues of safety and effectiveness.

6. Summary of Technological Modifications compared to Predicate Devices:

The technological modifications made to the subjected device compared to the predicate devices are summarized in the following table:

Predicate device	Modification summary (Proposed device)
Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) (K070547) (SV-S23FL35VS & SV-S25FL35VS)	SV-S23FL35 & SV-S25FL35: a) Change of code b) Change of tube supplier (material remains identical) c) Change of adapter design d) Change of process for embedding of filter in adapter from insert moulding to ultrasonic welding e) Change of adapter cap design f) Change of adapter cap material from PP to different grade of PP. g) Connection wing hub – tube from tetrahydrofurane solvent bonding to cyclohexanone solvent bonding h) Connection tube – adapter: from solvent to glue bonding i) Connection Surshield protector from cyano-acrylate glue to UV curing glue j) Change of specification for dead space volume k) Update of labeling

7. Summary of Verification Activities:

All necessary verification and validation tests have been performed for the Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield), to assure substantial equivalence to the predicate devices. Summary of all verification activities including acceptance criteria is given in the following table:

TEST	ACCEPTANCE CRITERIA
1. Visual inspection	When examined by normal vision or under 2.5 fold magnification, all components of the set are smooth, clean and free of flash, surface irregularities, detachable particles, and moulding or processing defects
2. Effective tubing length	The effective tubing length is 350 ± 20mm
3. Dead space volume	Dead space volume for sets with standard tubing: ≤ 0.40 ml Dead space volume for sets with microbore tubing: ≤ 0.20 ml
4. Air leakage (= integrity of set)	No leakage
5. Air leakage luer adaptor	No leakage at the luer connection (according to ISO 594-1 and ISO 594-2)
6. Liquid leakage luer adaptor	No leakage at the luer connection (according to ISO 594-1 and ISO 594-2)
7. Conical fitting	The conical fitting shall be within level 1-3 (according to ISO 594-1 and ISO 594-2)
8. Separation force of Luer slip tip connection	The fitting remains attached (according to ISO 594-1)
9. Separation force of Luer lock connection	The fitting remains attached (according to ISO 594-2)
10. Stress cracking on Luer conical fitting	No stress cracking on the conical fitting (according to ISO 594-1 and ISO-594-2)
11. Unscrewing torque of Luer lock fittings	The fitting remains attached when the fitting between the hub and a reference fitting is tested according to ISO 594-2
12. Ease of assembly	A satisfactory fit is achieved when tested according to ISO 594-2
13. Overriding resistance of Luer lock systems	When the fitting between the hub and a reference fitting is tested, the reference fitting shall not override the threads or lugs of the fitting under test (according to ISO 594-2)
14. Torque resistance cap – adapter	The torque force required to unscrew the cap from the adapter does not exceed 9 N.cm
15. Bonding strength tube – adapter	The force required for separating the tube from the adapter is 15 N minimum.
16. Bonding strength tube - wing hub	The force required for separating the tube from the wing hub is 15 N minimum.
17. Air flow choke test	Air bubbles escape out of the set when immersed under water and connected to an airline of 20 kPa (0.2 bar) effective pressure, to create an airflow through the set.
18. Flow rate	Flow rate for sets with standard tubing: 23G: ≥ 2.9 ml/min & 25G: ≥ 1.6 ml/min Flow rate for sets with microbore tubing: 23G: ≥ 1.7 ml/min & 25G: ≥ 1.5 ml/min
19. Bonding strength Surshield protector	The bonding strength between the Surshield protector and the SV-set is minimum 4 N
20. Misalignment of Surshield Protector	The angle measured axially from the cannula between the horizontally positioned wings and the vertically positioned Surshield protector does not exceed 15°.
21. Peel behaviour of blister	The blister is peeled by hand with minimal fibres and no paper splitting
22. Peel strength	The peel strength of the pack seal is minimum 0.15.kN/m
23. Package integrity	The integrity of the unit pack is minimum 4 kPa
24. Kink stability of tubing	Free of deformation and kinking
25. Filter performance testing	Same or better than predicate

The Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield), meet all acceptance criteria as indicated in table above. None of the obtained data raises any new issue of safety and effectiveness.

8. Additional Safety Information

The sterility of the Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield) is assured by using a validated sterilization method qualified in accordance with the requirements of EN ISO 11135-1 "Sterilization of health care products – Ethylene oxide – Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels resulting from EtO sterilization are in compliance with EN ISO 10993-7: "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals".

The 23G and the 25G Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield) are Externally Communicating devices, Circulating Blood, Limited Exposure (24 hrs). The devices' blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing".

The expiration dating for the 23G and the 25G Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield) have been established at 5 years which is the same as the cleared Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) (K070547).

9. Conclusion

The Surflo Winged Infusion Sets with Filter and Needle Protection (Surshield) manufactured by Terumo Europe N.V. and submitted in this 510(k) file are substantially equivalent in intended use, description, specifications, and technology/principles of operation, materials and performance to the following cleared devices:

Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) (K070547)

Differences between the devices do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 18, 2014

TERUMO EUROPE N.V.
Mrs. M.J. Aerts
Manager Regulatory Affairs
Interleuvenlaan 40,
3001 Leuven,
BELGIUM

Re: K133894
Trade/Device Name: SURFLO® Winged Infusion Set With Filter And Needle Protection (Surshield®)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 18, 2013
Received: December 20, 2013

Dear Mrs. Aerts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
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Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K133894

Device Name: Surflo® Winged Infusion Set with Filter and Needle Protection (Surshield®)

Indication For Use:

The Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) is intended to access the peripheral vascular system, for single-dose or short-term intravenous administration of fluids using a syringe or other compatible/appropriate devices. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needle stick.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed -S